IDRX 19 -

Antommaria Deposition Transcript

(Public document)

	Page 1
1	UNITED STATES DISTRICT COURT
	MIDDLE DISTRICT OF NORTH CAROLINA
2	
3	VICTOR VOE, by and :
1	through his parents and :
4	next friends, Vanessa Voe :
5	<pre>and Vance Voe, et al., : Plaintiffs, :</pre>
J	: CASE NO. 1:23-cv-864
6	vs. :
Ū	:
7	THOMAS MANSFIELD, in his :
	office capacity as Chief :
8	Executive Officer of the :
	North Carolina Medical :
9	Board, et al., :
	Defendants, :
10	: -
11	and :
11	DITTED E DEDCED in him.
12	PHILIP E. BERGER, in his : official capacity as :
12	President Pro Tempore of :
13	the North Carolina :
	Senate, and TIMOTHY K. :
14	MOORE, in his official :
	capacity as Speaker of :
15	the North Carolina House :
	of Representatives, :
16	Intervenor-Defendants. :
17	
18	Thursday, September 5, 2024
19	Virtual Deposition of:
20 21	DR. ARMAND H. MATHENY ANTOMMARIA,
22	
23	
24	
25	

	Page 2
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2	Thursday, September 5, 2024
3	Virtual Deposition of:
4	DR. ARMAND H. MATHENY ANTOMMARIA,
5	Called for oral examination by counsel for
6	the Intervenor-Defendants, pursuant to notice via Zoom
7	technology, before Melissa L. Clark, of Veritext
8	Legal Solutions, a Registered Professional Reporter
9	and Notary Public in and for the State of Maryland,
10	beginning at 9:36 a.m., when were present on behalf
11	of the respective parties:
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behavioral research involving humans; correct?

- A. I don't recall off the top of my head your characterization as being required by an act of Congress. But yes, it outlines basic ethical principles and the protection of human subjects and research.
- Q. And eventually the Belmont Report was published in the Federal Register, this final version in 1979; is that right?

MR. HASKEL: Objection to form.

THE WITNESS: Again, there are a variety of formats in which it was published. I had not recalled that it was published in the Federal Register, but your exhibit is that version of its publication.

BY MR. HILDABRAND:

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Q. So do you see on the left where it talks about summary of July 12th, 1974, the National Research Act, Public Law 93-348, was signed into law, therefore creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

Are you --

- A. So you're on page 23, 192, sir?
- Q. Correct. Yes.

1	A. Yes, I see in the left-hand column			
2	the summary that begins with the sentence that			
3	you've read.			
4	Q. Okay. So a layer of the so can			
5	you explain to me the process you understand of			
6	how the Belmont Report came about?			
7	A. So I know, sir, that in general			
8	there have been a variety of national bioethics			
9	commissions, which are either established by the			
10	executive branch or the legislative branch. I			
11	don't know that I have specific recall about the			
12	establishment of the commission that resulted in			
13	the Belmont Report.			
14	Q. So as a bioethicist, you're not			
15	familiar with the background of the Belmont Report			
16	besides just its existence and what's described in			
17	the Belmont Report?			
18	MR. HASKEL: Objection to form.			
19	THE WITNESS: Sir, that's an			
20	exceptionally broad question, and I understand the			
21	general history, particularly the issues about the			
22	inadequate protection of participates, even			
23	research that lead to the development of the			
24	Belmont Report, and the eventual establishment of			

the common rule, and institutional review boards.

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I'm just stating that I don't remember off the top of my head all of the proximate causes that resulted in the establishment of commission that offered the Belmont Report.

BY MR. HILDABRAND:

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Q. Feel free to answer the next question to turn to page 23-193, which would be page 3 in the PDF to the right-hand column there. You may be able to answer without reference to it, but I just wanted to -- I'm sorry, it's page 23-194. Sorry. So page 4, 23-194 on the right-hand column.

Was concern about the Tuskegee Syphilis Study one of the driving factors behind the establishment of the committee that drafted and prepared the Belmont Report?

MR. HASKEL: Objection. Foundation. You can answer.

THE WITNESS: The paragraph to which you're referring me refers to both atrocities that occurred in the Nazi concentration camps and although it's not stated, resulted in the Nuremberg trials, as well as the -- what's referred to as the Tuskegee syphilis study, and I

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would assume that Henry Beacher's publication of examples of unethical research was also part of the impetus for the establishment of the commission.

BY MR. HILDABRAND:

- Q. All right. Turning back a little bit to page 23-193, should be the third page in the PDF. In the middle column, do you see where the Belmont Report refers to -- describe something as experimental in the sense of new, untested, or different?
- A. One moment, sir. Yes, I see that sentence, sir.
- Q. And then the Belmont Report opines that just because something is experimental and it's new, untested, or different, does not automatically place it in the category of research; right?
 - A. That's what it says, sir.
- Q. So as the Belmont Report understands it, just because something is researched does not make it -- sorry.

As the Belmont reports understands it, just because something is experimental does not mean that it is researched; correct?

	1490 210				
1	CERTIFICATION				
2	I HEREBY CERTIFY that I am a Court Reporter				
3	and Notary Public.				
4	I FURTHER CERTIFY that the witness was				
5	sworn to testify to the truth.				
6	I FURTHER CERTIFY that the following is,				
7	to the best of my ability, a true and accurate				
8	transcription of the testimony taken stenographically				
9	by me at the time, place, and date herein before				
10	set forth.				
11	I FURTHER CERTIFY that I am neither a				
12	relative, employee, attorney nor counsel to any of				
13	the parties to the action, and that I am neither a				
14	relative nor employee of such attorney or counsel				
15	and that I am not financially interested in the				
16	action.				
17	Milisinh Clark				
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19	Court Reporter				
20	Melissa L. Clark				
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ERRATA SHEET

IN RE: Victor Voe, et al. v. Thomas Mansfield, et al., and Philip E.

Berger, et al.

DEPO OF: Armand Antommaria TAKEN: September 5, 2024

DO NOT WRITE ON TRANSCRIPT, ENTER ANY CHANGES HERE

PAGE #	LINE #	CHANGE	REASON
1	18	"September 9" to "September 5"	Correction
4	21	"Change Practice Guidelines We Can Trust" to "CMS OpenPayments for Safer.pdf"	Correction
9	10	"deposition" to "report"	Mistranscription
24	15	"document that you in" to "document that you reviewed in"	Mistranscription
28	1	"no" to "on"	Mistranscription
28	7	"normal" to "formal"	Mistranscription
32	20	"bronchiolitis respiratory" to "bronchiolitis, respiratory"	Mistranscription
32	23	"We" to "They"	Mistranscription
33	3	"ethics center" to "Ethics Center"	Mistranscription
33	18	"rounding areas" to "rounding in areas"	Mistranscription
42	12	"wildly" to "widely"	Mistranscription
45	19-20	"nor to my general understanding, the term" to "nor to my general understanding of the term,	Mistranscription
55	14-15	"credentialing, licensing. And malpractice litigation, because" to "credentialing, licensing, and malpractice litigation. Because"	Mistranscription
56	10	"determination, so" to "determination. So"	Mistranscription
63	20	"consent" to "assent"	Mistranscription
65	24	"peripheral" to "preferable"	Mistranscription
71	4	"legal" to "clinical"	Mistranscription
72	9	"care" to "time"	Mistranscription
80	9	"colleagues" to "colleagues'"	Mistranscription
83	6-7	"next of the" to "next page of the"	Mistranscription
83	12	"noncompliant" to "not competent"	Mistranscription

85	25	"on" to "of"	Mistranscription
87	25	"exact time" to "effect on"	Mistranscription
90	17	"he'd use," to "that had used"	Mistranscription
94	15	"." to "?"	Mistranscription
96	17	"my question" to "language"	Mistranscription
97	4	"2018s" to "2010s"	Mistranscription
100	25	"seeking" to "taking"	Mistranscription
122	22	"participates" to "participants"	Mistranscription
122	25	"common rule" to "Common Rule"	Mistranscription
123	4	"offered" to "authored"	Mistranscription
124	25	"researched" to "research"	Mistranscription
126	12	"both sides, to where" to "locations where"	Mistranscription
127	3-4	"clinical practice has different goals and methods from research or experimentation" to ""clinical practice has different goals and methods from research or experimentation""	Misquotation
128	8	"no" to "no,"	Mistranscription
129	16	"a" to "the"	ļ ————————————————————————————————————
129	10		Mistranscription
129	23	"clinical pathogens research" to "clinical effectiveness research"	Mistranscription
130	17	"improving" to "unproven"	Mistranscription
132	1	"." to "?"	Mistranscription
134	4	"autonomy non-malfeasance injustice" to "autonomy, nonmaleficence, and justice"	Mistranscription
136	2	"your" to "their"	Mistranscription
		"and effective," to "and effective,""	
136	19		Mistranscription
136	22	"since" to "sentence in"	Mistranscription
137	2	"we'd" to "when I'd"	Mistranscription
137	15	"Register in" to "Register. In"	Mistranscription
		"procedure. What" to "procedure, what"	
138	17		Mistranscription
138	18	"normal" to "formal"	Mistranscription
138	20	"wouldn't" to "would"	Mistranscription
141	12	"mass" to "masked"	Mistranscription
141	16	"weather" to "what were"	Mistranscription
141	23	"knew" to "know"	Mistranscription

142 154 154 156 158 163 167	24 5 25 19 6 11	"behind" to "designed" Delete "[sic]" "Pediatric" to "Pediatrics" "we" to "they" "suggestively seen" to "suggested	Mistranscription Mistranscription Mistranscription
154 156 158 163	25 19 6	"Pediatric" to "Pediatrics" "we" to "they"	Mistranscription
156 158 163	19	"we" to "they"	
158 163	6	-	Migtpapaggintian
163		"suggestively seen" to "suggested	Mistranscription
	11	routinely"	Mistranscription
167		"policy to but" to "Policy. But"	Mistranscription
	3	"punitive" to "putative"	Mistranscription
173	12	"driving" to "deriving"	Mistranscription
175	17	"universal" to "intellectual"	Mistranscription
185	16	"exactly" to "correctly"	Mistranscription
192	12	"experience." to "experience.""	Mistranscription
199	8	"document, Treatment," to ""document, Treatment,"	Mistranscription
201	6	"under Funding Information," to "under "Funding Information,"	Mistranscription
201	9	"e-mail," to "in the"	Mistranscription
201	19	"system" to "systematic"	Mistranscription
204	20	"imposition for" to "utilization of the"	Mistranscription
205	2	"corrected" to "correct"	Mistranscription
205	10	"band" to "ban"	Mistranscription
206	20	"analyzing" to "adolescent"	Mistranscription
206	23	"I" to "it"	Mistranscription
207	12	"immobilization" to "utilization"	Mistranscription
208	24	"adolescents" to "adolescents"	Mistranscription
209	8	"bottom some highlights" to "rebuttal report"	Mistranscription
211	5	"Systematic Review" to "systematic review"	Mistranscription
211	17	"off-sided" to "oft cited"	Mistranscription
212	9	"off-sided" to "oft cited"	Mistranscription
214	15	"off-sided" to "oft cited"	Mistranscription
215- 216	23-	Add quotations marks to the whole question	Mistranscription
215	25	"consider." In" to "consider in"	Mistranscription
216	19	"treatments?" to "treatments"?"	Mistranscription
217	16	"space" to "base"	Mistranscription
219	2	"function."" to "function"?"	Mistranscription

222	10	"Bero where he said" to "your report"	Mistranscription
225	18	"we" to "they"	Mistranscription
229	4	"enforce" to "endorse"	Mistranscription
230	10-11	"endocrine societies" to "Endocrine Society's"	Mistranscription
232	1	"opinions" to "information"	Mistranscription
235	5	"fellow" to "Fellow"	Mistranscription
235	16	"BAP" to "AAP"	Mistranscription
236	16	"associates" to "associations"	Mistranscription
242	20	"negative" to "analog"	Mistranscription
244	4	"position" to "information"	Mistranscription

State of Ohio
County of Hamilton

Under penalties of perjury, I declare that I have read by deposition transcript, and it is true and correct subject to any changes in form or substance entered here.

10/09/2024	Armand Antommaria
Date	Armand Antommaria
Sworn and subscribed to	before me this 9th of October, 2024.
PERSONALLY KNOWN	OR I.D. Ohio Drivers License

Notary Public in and for

the State of [STATE] at Large.

My commission expires: 09/30/2027

Virginia



Notarized remotely online using communication technology via Proof.